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| 09/748,789 | 12/22/2000 | Anthony P. McHale | 11067/1090 | 3325 |

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| EXAMINER | |
|---|---|
| LI, QIAN JANICE | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1632 | 18 |

DATE MAILED: 12/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Applicati n No. | Applicant(s) | |
|---|---|---|---|
| | 09/748,789 | MCHALE ET AL. | |
| | Examiner | Art Unit | |
| | Q. Janice Li | 1632 | |

*-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *18 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-4,10-19,26,30-32 and 36-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,10-19,26,30-32 and 36-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 March 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

The amendment and response filed 8/18/03 has been entered. Claim 49 has been canceled. Claims 1, 3, 4, 26, 30-32 have been amended. Claims 1-4, 10-19, 26, 30-32 and 36-48 are pending and under current examination.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The prior rejection of claim 26 under 35 U.S.C. 112, first paragraph, is withdrawn in light of claim amendment limiting the pre-sensitizing to an in vitro process.

Claims 4, 18, 19, 38-47 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered when determining whether the disclosure satisfies the enablement requirements and whether undue experimentation would be required to make and use the claimed invention are summarized in *In re Wands*, (858 F2d 731, 737, 8 USPQ 2d 1400, 1404, (Fed Cir.1988)). These factors include but are not limited

to the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability of the art, the breadth of the claims, and amount of direction provided. The factors most relevant to this rejection are the scope of the claims relative to the state of the art and the levels of the skilled in the art, and whether sufficient amount of direction or guidance are provided in the specification to enable one of skill in the art to practice the claimed invention.

Step (d) of claim 4 requires applying ultrasound at a frequency and energy sufficient to cause disruption of sensitized red blood cells, which encompasses applying ultrasound *in vivo* to the loaded red blood cells. However, the claims or the specification fails to teach how the ultrasound could reach the red blood cells at sufficient amount and location so that the loaded RBCs would be disrupted. The specification teaches an in vitro circulating system as a model for in vivo vascular system (example 9), however, the specification fails to teach how such system correlates with the *in vivo* blood circulation system, whether the system is an art-recognized model, how the ultrasound could be applied *in vivo* to achieve targeted RBC disruption, particularly considering that the blood vessels are deeply embedded in the soft tissue and organs, and the fast blood flow would carry away the RBCs as soon as they are introduced into the circulation. Therefore, it appears that the guidance is insufficient for those intending to practice the invention.

Accordingly, in view of the limited guidance, the lack of predictability of the art and the nature of the claims, one skill in the art could not practice the invention without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The prior rejection of claim 49 under 35 U.S.C. 112, second paragraph is moot because claim 49 is now canceled.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (f) he did not himself invent the subject matter sought to be patented.

The prior rejection of claims 1, 3, 10, 14-17, 26, 30, 31, 35, 37, and 49 under 35 U.S.C. 102(f) over U.S. patent 6,495,351, is withdrawn because applications indicated that the instant application and the cited patent is commonly owned *at the time of Applicant's invention.*

Claims 26, 30, 31 stand rejected under 35 U.S.C. 102(b) as being anticipated by *Mouneimne et al* (US 5,236,835).

In 8/18/03 paper, applicants argue that the red blood cells of *Mouneimne et al* is distinguishable over the instant claimed red cells that have efficient loading characteristics and are more susceptible to disruption by exposure to a stimulus, and pointing to example 2 of the specification.

The argument has been fully considered but not found persuasive. This is because the claims encompass the red blood cells taught by *Mouneimne et al.* In *Mouneimne* reference, the RBCs are electrosensitised by presensitizing, loading, and sensitizing in a sequential process since the cells are in the loading agent suspension and the electroporation occurs prior and after the loading (presensitizing and loading). Example 2 only compares the differences for cells with or without electrosensitizing, and does not provide evidence that the product in the cited art is structurally or functionally different compared to the instantly claimed. The newly added claim recitation, "hypersensitive to a disruptive stimulus" states intended goal of electrosensitising, would not carry patentable weight in determining the novelty of the claimed product. Further, as indicated in the previous Office action, claim 26 only requires "obtainable", thus, the red blood cell as claimed is not limited by the recited method. Therefore, *Mouneimne et al* anticipate the instant claims.

Claims 26, 30, 31 stand rejected under 35 U.S.C. 102(b) as being anticipated by *Lizano et al* (Biochimica Biophysica Acta 1998;1425:328-336).

Applicants presented similar argument for this rejection as to *Mouneimne et al* reference, which has been addressed above, will not be reiterated.

Claims 26, 30, 31 stand rejected under 35 U.S.C. 102(b) as being anticipated by *Mitchell et al* (Biotech Applied Biochem 1990;12:264-75).

Applicants presented similar argument for this rejection as to *Mouneimne et al* reference, which has been addressed above, will not be reiterated.

Claims 26, 30, 31 stand rejected under 35 U.S.C. 102(b) as being anticipated by *Zimmermann et al* (US 4,289,756).

Applicants presented similar argument for this rejection as to *Mouneimne et al* reference, which has been addressed above, will not be reiterated.

The prior rejection of claims 26, 30-32 under 35 U.S.C. 102(b) as being anticipated by *Magnani et al* (US 6,139,836) is withdrawn in view of claim amendment.

Claims 1, 3, 10, 13-15, 17, 26, 30-32, 37 are newly rejected under 35 U.S.C. 102(b) as being anticipated by *Haritou et al* (Clin Hemorheol Microcirc. 1998;19:205-217).

The amended claims add new limitation that the first step of pre-sensitizing and the second step of loading are temporally separated.

*Haritou et al* teach a method for loading a red blood cell with an agent comprising: presensitizing the RBC by electroporation *in vitro*, followed by a second step of loading said RBC with an agent. They teach applying 5 exponential decay

pulses of 2kV/cm field strength for 0.8-millisecond pulse duration (pre-sensitizing), then immediately add the agent to be loaded (page 209, § 3.1), wherein the pre-sensitizing is performed before loading, and the two steps are temporally separated. The red blood cells produced by *Haritou et al* are electrosensitized, thus meet claim limitation. Therefore, *Haritou et al* anticipate instant claims.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 10, 13-17, 26, 30, 31, 36, 37, 48 stand rejected under 35 U.S.C. 103(a) as being unpatentable over *Mitchell et al* (Biotech Applied Biochem 1990;12:264-75), in view of *Ortiz et al* (Mutation Res 1995;327:161-9).

In 8/18/03 response, applicants argue that the cited prior art do not teach separate steps of sensitization and loading, and Ortiz et al teach a method that the electrical treatment and the permeation occur as a single step, not done separately. Applicants further argue that neither Mitchell nor Ortiz teaches or suggests that electroporated cells are pre-sensitized and can be loaded with an agent at a later time, and there are no motivation taught to combine the references.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by

combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, *Mitchell et al* teach that loading two proteins into RBCs by electroporation and the content release of red cells are positively linked to increased pulse length, frequency, and intensity of the electric field, they teach using a electric field ranges from 6-8 kv/cm from 5-40 microseconds. *Ortiz et al* teach a method of loading CHO cells with two (protein) enzymes using different combinations of single- and double-dose electroporation, they teach that separate loading of two enzymes as an alternative protocol for certain need, and teach that once the cells have been electroporated, they would resist a second electroporation and remain viable (2nd paragraph, right column, page 167).

Here, the method steps meet claim limitation, i.e. the first step of loading taught by *Ortiz et al* is considered pre-sensitizing relative to the second step of loading regardless whether *Ortiz et al* expressly suggested the pre-sensitizing, and the second step of eletroporation is considered as a sensitizing step after loading. The claims do not require that the pre-sensitizing or sensitizing step excluding the process of loading, particularly considering the sensitizing could be done after loading. Moreover, *Ortiz et al* clearly teach the influence of multiple-electroporation on cell membrane and viability.

Accordingly, given the multiple protocols of loading RBCs with multiple agent known in the art, this limitation (single or multiple regimens of electroporation) would fall

within the bounds of the optimization of loading. Thus, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify the methods taught by *Mitchell et al*, and *Ortiz et al* by simply using the protocol of multiple doses of electroporation for loading multiple agents into RBCs with a reasonable expectation of success.

Applicants also argue that the combined teaching does not result in the electrosensitized cells of the present invention wherein the electrosensitised RBCs loaded with a higher amount of agent and hypersensitive to a disruptive stimulus. In response, it is noted that the combined teaching results in a process, wherein the RBCs receive the same presensitizing, loading, and sensitizing treatment, wherein the second loading is temperately separated from the presensitizing, thus, the RBCs would have the same properties of the claimed RBC. Therefore, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Mitchell et al* (Biotech Applied Biochem 1990;12:264-75) and *Ortiz et al* (Mutation Res 1995;327:161-9) as applied to claims 1-3, 13-17, 26, 30, 31, 36, 37, 48 above, and further in view of *Magnani et al* (US 6,139,836).

Claim 32 is drawn to an electrosensitized and loaded RBC comprises PEG.

*Mitchell et al* (Biotech Applied Biochem 1990;12:264-75) and *Ortiz et al* teach the electrosensitized and loaded RBCs. The combined teaching does not suggest encapsulating the RBCs.

*Magnani et al* teach using PEG capsule as a pharmaceutically acceptable carrier for the ease of in vivo delivery of loaded erythrocytes (column 7, line 63).

Accordingly, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify the methods taught by *Mitchell et al, Ortiz et al,* by simply encapsulating the loaded RBCs as taught by *Magnani et al* with a reasonable expectation of success. The ordinary skilled would have been motivated to do so because the PEG encapsulation protects the loaded RBCs from deleteriously effect during delivery. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

The prior rejection of claims 4, 19, 38-47 under 35 U.S.C. 103(a) as being unpatentable over *Mitchell et al* (Biotech Applied Biochem 1990;12:264-75) and *Ortiz et al* (Mutation Res 1995;327:161-9) as applied to claims 1-3, 13-17, 26, 30, 31, 36, 37, 48 above, and further in view of *Halaka* (US 6,071,480) is withdrawn in view of the following new ground of rejection.

Claims 1-4, 11, 16, 18, 19, 36, 38, 39, 41-47 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over *Haritou et al* (Clin Hemorheol Microcirc. 1998;19:205-217), *Lizano et al* (Biochim Biophys Acta 1998;1425:328-36), taken with *Kost et al* (US 6,041,253), *Unger et al* (US 6,638,767), and further in view of *Liu et al* (Pharm Res 1998;15:918-24).

Claims are drawn to presensitizing and electrosensitizing red blood cells, loading the RBCs with single or multiple agents, and then effectuating substantial release of said agent(s) by applying ultrasound, wherein the presensitizing could be applying an electrical field, ultrasound, or osmotic pressure.

*Haritou et al* teach using red blood cells as a carrier for encapsulating agents for in vivo drug delivery, and applying electric field before and after loading the RBCs as discussed above.

*Lizano et al* teach encapsulating ADH and ALDH into human erythrocytes by electroporation, loading, and resealing the loaded RBCS (abstract).

*Kost et al* teach transdermal delivery of drugs using the combination of electric field and ultrasound, wherein the drug could be encapsulated in a carrier particle (abstract, and column 10, lines 57-67). They teach that combination of electrical field and ultrasound can be applied to any membrane including any cell wall or membrane for agent delivery or extraction, so that the intensity levels of the electrical fields will be much lower and thus less damage to the membranes (column 10, lines 22-39). They further teach that besides ultrasound, osmotic pressure or magnetic field could also be used (§ bridging columns 9 & 10).

*Unger et al* teach a method for delivering a compound to a cell (loading) comprising loading the cells with a gene gun or electroporation, and in combination with ultrasound, wherein the ultrasound could be applied before, after and/or simultaneously with the loading process to further increase the efficiency of compound delivery (column 24, lines 8-15).

*Liu et al* teach that ultrasound could transiently permeabilize biological membranes such as red blood cells, thereby facilitating delivery of large compounds *in vivo*. Although *Liu et al* do not specifically teach the field strength levels for *in vivo* use, at the time ultrasound has been widely used in clinical diagnosis and treatment, the skilled in the art would have known to optimize the ultrasound levels for agent release based on the ultrasound dosing regimen for other clinical use.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the methods taught by *Haritou et al, Lizano et al, Kost et al, Unger et al*, and *Liu et al* by loading the RBCs with the combination of electroporation/ultrasound or electroporation/osmotic pressure, and releasing the loaded content by ultrasound with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to modify the claimed invention because the combination of electric field and another mechanical force would facilitate the loading and reduce electric damage to cell membrane as taught by *Kost et al* and *Unger et al*; and the ultrasound would promote or enhance the agent release particularly when the agent is a large compound such as proteins and DNAs as taught by *Liu et al*. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Claims 12 and 40 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over *Haritou et al* (Clin Hemorheol Microcirc. 1998;19:205-217), *Lizano et al* (Biochim Biophys Acta 1998;1425:328-36), *Kost et al* (US 6,041,253), *Unger et al*

(US 6,638,767), and *Liu et al* (Pharm Res 1998;15:918-24) as applied to claims 1-4, 11, 16, 18, 19, 36, 38, 39, 41-47 above, and further in view of *Franco et al* (US 4,478,824).

Claims 12 and 40 are drawn to loading RBCs with osmotical shocking or hypotonic dialysis. The combined teachings of *Haritou et al*, *Lizano et al*, *Kost et al*, *Unger et al*, and *Liu et al* do not teach loading with hypotonic dialysis.

However, long before the instant effective filing date, *Franco et al* teach a method of introducing desired materials into the red blood cells using trans-membrane osmotic gradient (hypotonic dialysis, see e.g. abstract).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the methods taught by *Haritou et al, Lizano et al, Kost et al, Unger et al*, *Liu et al,* and *Franco et al* by loading the RBCs with either electroporation or osmotic shock with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to modify the claimed invention because given the numerous means of loading RBCs known in the art, the skilled artisan could easily select any one of the loading methods. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 10-19, 26, 30-32, and 36-48 stand or newly rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-21 of U.S. patent 6,495,351. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed method in the cited patent encompasses the instant claims, and the subject matter is fully disclosed in the cited patent.

The amended claims are obvious over claims 19-21 of the cited patent because the subject matter is fully disclosed throughout the specification of the cited patent. Therefore, the rejection stands.

The newly included claims are drawn to using ultrasonic and osmotic energy for sensitizing or loading red blood cells and releasing the loaded agents. It is noted that the subject matter is also fully disclosed throughout the specification of the cited patent. Therefore, the claims of the cited patent and instant claims are co-extensive.

Claims 4, 18, 19, 38-47 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-14 of co-pending Application No. 09/748,063.

The amended claims are obvious over claims 19-21 of the cited patent because the subject matter is fully disclosed in the specification of the cited patent. Therefore, the rejection stands.

***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942 (571-272-0730, after the Office relocation in January, 2004). The examiner can normally be reached on 9:30 am - 6 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

JANICE LI
PATENT EXAMINER

Q. Janice Li
Patent Examiner
Art Unit 1632

DEBORAH J. REYNOLDS
SUPERVISORY PATENT EXAMINER
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QJL
November 19, 2003